

Tentative Agenda

ADVANCES AND NEW PARADIGMS IN PHARMACEUTICAL REGULATORY AFFAIRS

Organized by Pharmexcil in collaboration with CDSCO, EZ, Kolkata &

Drugs Control Administration, Govt. of Sikkim, Sikkim.

20th Mar 2020, Sikkim

TIME	PROGRAMME	
09.30 to 10.00 am	REGISTRATION	
INAUGURAL SESSION		
10:00 to 10:30 am	Inaugural Ceremony (10.00am-10.10am) Address by Guests <ul style="list-style-type: none">• Shr. Ravi Uday Bhaskar Pharmexcil-DG• Dr. A. Ramkishan DDC (I), CDSCO East Zone, Kolkata• Dr. T. K. Rai Additional Director, DCA-Sikkim.	
TECHNICAL SESSION		
10.30 to 11.15 am	Experience of Transformation of Culture with respect to Quality	Dr. Upendra S. Quenim Vice President-Swiss Garnier SIKKIM (TBC)
11.15 to 11.30 am	Tea Break	
11.30 to 12.15 pm	Recent Advancements in Indian drug Regulations & draft amendment of schedule M.	Dr. A. Ramkishan Dy. Drugs Controller (India), CDSCO , East Zone Kolkata
12.15 to 01.00 pm	Regulatory preparedness for USFDA Audits - Key gaps between Requirements & practices with observations made (483) and warning letters	Dr. Vipul Doshi President-Quality Zydus Cadila Ltd. Ahmedabad-Gujarat (TBC)
01.00 to 02.00 pm	Lunch break	
02.00 to 3.00 pm	Data Integrity with special emphasis on Audit Trails.	Dr. Pramendra Chandore QA/QC Head Sun Pharma Ltd. Sikkim (TBC)
03.00 to 03.15 pm	Tea Break	
03.15 to 04.00 pm	Pharma Digitalized World- Cyber security controls/ Role of AI in Data Monitoring & Data Analytics in Pharma Operations	TBD
04.00 to 04.30 pm	Panel Discussion / Q&A	
04.30 to 5.00 pm	Post conference Evaluation followed by Closing ceremony	